Patient-Oncologist Communication Regarding Oral Chemotherapy during Routine Office Visits

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Introduction

As oral chemotherapy agents are increasingly developed and used, pharmacotherapy in oncology care is shifting from intravenous formulations administered under the close and watchful eye of clinicians to therapies that are self-administered in the privacy of a patient's home. [1] With this shift comes the need for oncologists to assess and support medication adherence, in addition to managing treatment toxicities. [2] National practice standards and guidelines have been published in an effort to aid oncology practices in the safe administration and management of oral chemotherapy.[3,4] Despite the known importance of medication counseling to patient adherence and safe medication practices, medical record documentation is known to be incomplete for medication counseling,[5] and little is known about how oncologists address medication counseling during routine office visits.

Medication adherence is the process by which patients take their medications as prescribed, including whether a patient initiates taking the medication, how they implement taking the medication, and whether they discontinue taking the medication.[6] Recent studies have revealed adherence to oral chemotherapies to be highly variable— ranging from as low as 23% to as high as 97%.[7] Several factors have been associated with non-adherence, including adverse side effects, concomitant drug burden, and low social support.[8] Many cancer hospitals and other oncology care providers have developed interventions that specifically target those receiving oral chemotherapy treatment.[9] Studies of these interventions have highlighted their inconsistent ability to enhance patients' medication adherence as well as challenges accompanying attempts to support self-administered cancer therapy.[10,11] Although a recent systematic review illustrated the potential for pharmacy-led interventions to reduce treatment-related side effects and improve

medication adherence[12], the poor quality of those studies reviewed, and those included in other similar reviews[10,11], simultaneously highlight ongoing gaps in knowledge.

Oral chemotherapy is unique in its frequent use of repeated treatment-rest cycles, concerns regarding toxicity, evidence of overuse, and need for ongoing symptom monitoring—all of which make counseling needs complex. Capecitabine is no exception. An oral chemotherapy agent that is dosed based on a patient's weight and height, capecitabine is similar to other oral chemotherapies in it is taken twice daily on a schedule of two weeks on and one week off,[13] and has been reported to be both under- and over-used by patients.[14–22]

Despite the often involvement of multiple clinicians in the oncology setting, oncology patients report physicians as their primary source of information regarding chemotherapy.[23] Importantly, a recent study found oncology patients who reported a high satisfaction with the information they received regarding the impact of their therapy were more adherent.[8] Such finding is consistent with that from other clinical contexts where patient-physician communication repeatedly has been found to be associated with patients' adherence to prescribed medications. [24,25] Despite the likely importance of oncologist communications to oral chemotherapy adherence, to our knowledge, no prior study has used observation of oncologist-patient office visit conversations to understand how oncologists assess and support patient adherence to oral chemotherapy.

Using audio-recordings for patients with colorectal cancer identified from the Verilogue Point of Practice database (http://www.verilogue.com), we describe patient-oncologist office-based discussions of oral chemotherapy treatment. Of particular interest was the extent to which oncologists provide medication information (i.e., medication name, purpose, dosage, duration,

and side effects) and offer strategies for managing medication side effects. We also describe how oncologists assess their patient's adherence to prescribed oral chemotherapy.

Methods

Study Population and Data Source

The Verilogue Point-of-Practice database is described in detail elsewhere.[26–29] In brief, Verilogue staff identify and recruit physicians from diverse practices and specialties to develop the Point-of-Practice database. Only patients who consent to having their encounter audio-recorded are included in the database.

For this study, Verilogue staff identified 25 outpatient encounters with a medical oncologist in the United States between January 1, 2014 and December 31, 2017 for which the patient: 1) was aged 19 years or older, 2) was diagnosed with colorectal cancer, and 3) had capecitabine listed as a current treatment. In addition to audio-recordings and transcripts, the Verilogue database contains structured information on the patient's gender, race, age, and current chemotherapy medications as well as the treating oncologist's gender and years in practice. The Institutional Review Board (IRB) at the University of North Carolina at Chapel Hill approved this study as exempt.

Qualitative Content Analysis

Using Qualtrics software [30], we developed a structured coding worksheet to identify and describe the medication counseling content present in patient-oncologist office visit discussions. To develop the coding items, we initially used results from a scoping review we are completing to determine the content of patient-clinician communication previously evaluated for its association with oral chemotherapy adherence. This resulted in the inclusion of codes specific to

the assessment and management of side effects, financial access assistance, logistical assistance accessing the medication, and concurrent medication management. In addition, to capture the comprehensiveness of the medication information provided by the oncologist, we used the Medication Communication Index (MCI).[31] The MCI includes items for the clinician's provision of medication name, purpose or justification, duration, adverse effects, and dosage. Finally, for medication adherence assessment, we considered the conceptual framework proposed by Vrijens and colleagues to code both therapy continuation and implementation.[6] An assessment of continuation was captured if the oncologist asked the patient about his/her continued use of capecitabine or willingness to complete a subsequent treatment cycle(s). Implementation assessments were recorded if the oncologist asked the patient or the patient volunteered information about missed doses, doses taken per day, or modifications to their medication taking behavior. We also included an item to capture whether or not the oncologist, patient, or both mentioned the availability of a separate program or staff member available to provide medication assistance or support. A number of these codes are consistent with the American Society of Clinical Oncology (ASCO) Quality Oncology Practice Initiative (QOPI) Certification Program Standards (e.g., evaluation of treatment-related toxicities and patient adherence when chemotherapy is administered outside the healthcare setting).[3] In addition to using these *a priori* determined components of medication counseling, research team members iteratively read and identified themes from batches of two office visit transcripts independently, and then met to discuss identified themes. Using this approach, we developed codes to capture details regarding the content of side effect management discussions. For example, we developed items specific to each body system that captured whether or not a side effect was discussed and/or endorsed as present by the patient, and whether or not self-management strategies specific to that side effect

were discussed. We also developed a code for the discussion of treatment phase (i.e., pre-treatment initiation, mid-treatment course or post-treatment), and concomitant infused chemotherapy use. Each item was coded as having occurred regardless of who initially raised the topic.

Coding was completed in rounds, with two coders (B.N. and B.W.) iteratively coding five transcripts independently and then meeting to discuss results. Within each round, coders reviewed two of the same transcripts. A separate lab member calculated interrater reliability scores for the double-coded transcripts (n=5).[32] Cohen's kappa was calculable for 24 items. For items where Cohen's kappa statistic was <0.55 (n=4), we re-coded the items using consensus coding. For the other items, the kappa score ranged from 0.55 – 1.00 (mean 0.87). For additional items (n=19) for which insufficient variability existed in the coded responses for a Cohen's kappa to compute, percent agreement between the two coders was 100 percent for each item.

Results

Study Population

Twenty-four encounters were included in the analyses. One encounter was with a patient who had completed capecitabine therapy and was therefore excluded. The demographic and clinical characteristics of the patient sample are presented in Table 1. Patients were seen by seventeen different oncologists who were primarily male (n=15) and practicing between 3 and 10 years (n=11). Office visit recordings ranged in length from 3-35 minutes, averaging 14 minutes (median time of 10 minutes).

Medication Information

All visits included the word "capecitabine" or its brand name. All visits also included a discussion of associated side effects. Over the course of a visit, patients who had not initiated therapy were generally provided the recommended basic elements of medication information (e.g., medication name, dosing frequency, therapy duration, number of tablets per dose, and adverse effects). Conversely, office visit discussions for patients in the midst of their treatment course contained less of this information. For example, patients who were mid-course were often not reminded of the purpose of the medication or the planned duration of therapy. Nor were they commonly counseled on either the prescribed frequency of medication administration or the number of tablets to take for each dose.

Therapy Continuation and Implementation

All patients who had initiated capecitabine were assessed for their continued use of the medication. Most encounters included a brief assessment only such as:

> **Oncologist**: *So you continue taking [capecitabine] by mouth?*
> **Patient**: *That is correct.*
>
> Case 541, mid-treatment

On the other hand, oncologists' assessments of therapy implementation (e.g., missed doses) among patients who had initiated therapy was more sporadic, and when such discussions occurred, they varied in scope. These discussions ranged from simple, seemingly incidental statements from the patient that a dose had been missed to in-depth assessments initiated by the oncologist that specifically asked about medication taking behavior. The quotes below illustrate such variability.

> **Oncologist**: *Okay. And let's go ahead. This will be cycle number four. Okay, let's see if we have the orders in. Yep, we have the orders in and everything, and you have your [capecitabine]?*

Patient: *Yes.*
Oncologist: *Excellent.*
Patient: *Yeah, I missed a day in, uh, because they made, well they called, I ordered it on Thursday. [INAUDIBLE] Tuesday.*

Case 43322, mid-treatment

Oncologist: *And you're taking, um, three in the morning and three in the evening?*
Patient: *Yes.*
Oncologist: *Okay So it's been seven days already and when will you finish? See it over there? [DATE] so Tuesday, last Tuesday is when you started?*
Patient: *Yes.*
Oncologist: *So it's going to be probably [DATE] will be, the, [DATE] will be the last one, right? That's what I'm thinking.*

Case 61386, mid-treatment

Side effect Management

At least one side effect was discussed in all encounters, commonly gastrointestinal (GI) system-related side effects. Encounters with patients who had yet to initiate treatment discussed common side effects reported with capecitabine and included a discussion of self-management strategies to try should the patient become symptomatic. Once therapy had been initiated, discussion of self-management strategies in absence of symptom presentation was rare. Instead, once therapy had been initiated side effect self-management strategies were offered in a reactive fashion (i.e., only when the patient endorsed having the side effect). For example, one patient was provided with the following suggestion:

Patient: *My tongue on both sides was sore like I'd bitten it, but I hadn't.*
Oncologist: *Have you ever tried some saltwater with… bicarbonate and just swishing it around and spitting it out?*

Case 19249, mid-treatment

Concurrent Medication Management

Patients' use of concurrent oral medications were also discussed. These discussions typically focused on patients' use of medications for the management of capecitabine's side effects (e.g. acetaminophen, loperamide, iron supplements). Discussion of medications for a

comorbid condition was rare. The following quote illustrates a typical discussion of concurrent medications:

> **Patient**: *I'm doing good.*
> **Oncologist:** *Any problems?*
> **Patient:** *Well, I've been nauseous.*
> **Oncologist:** *A little bit of nausea. Are you taking your [prochlorperazine]?*
> **Patient:** *Yes, I need to get a refill on it, too.*
>
> Case 1207, mid-treatment

Medication Access

Discussions regarding how medications would be obtained and other logistical assessments were common. These types of assessments were directed primarily at the oncologist trying to understand when the medication would be in the patient's possession. For example, oncologists often coordinated subsequent visits based on the patient's access to capecitabine. For example:

> **Oncologist**: *"… how many days does it take for the pharmacy to deliver the medicine?*"
> **Patient**: "*Um, a couple of days*."
> **Oncologist**: "*Yeah. That's fine?*"
> **Patient**: *Yeah. That's a couple of days.*
> **Oncologist**: "*Okay, so why don't we get together that Monday. Um, we'll just make sure everything is fine and then order the next [cycle].*"
>
> Case 62823, mid-treatment

In four office visits, we observed an oncologist inquiring about the patient's financial access to capecitabine: three encounters with patients who had yet to initiate therapy and once with a patient mid-course.

References to Other Available Programs and/or Clinician Support

No encounter contained a discussion of another medication support program or other clinician that might be available to the patient or their caregiver(s) to assist with medication management or support.

Discussion

Patient medication adherence is a common and costly challenge that is relatively new within the context of oncology care.[33] Using audio-recordings from a national sample of oncology office visits, we identified the content of and gaps in routine medication counseling received by patients with colorectal cancer prescribed capecitabine. We found that although virtually all patients discussed continuation of their oral chemotherapy with their oncologist, discussions addressing whether patients were taking their chemotherapy as prescribed were less commonplace. Likewise, while we found all office visits included discussion of the common side effects to therapy, discussion of self-management strategies patients could employ were more varied, and rarely provided pre-emptively once therapy was initiated. Instead, once a patient initiated therapy, self-management strategies seemed to be provided to patients only after they presented with a side effect.

Our findings illustrate that oncologists commonly engage in medication counseling with their patients prescribed capecitabine. Yet, the counseling we observed was often void of recommended best practices. For example, oncologists often did not directly ask patients about their therapy implementation (e.g. whether they missed, skipped, or cut doses). By not asking about therapy implementation, oncologists place the responsibility of reporting non-adherence on the patient. Because patients may not understand the importance of disclosing medication adherence behaviors and/or be comfortable divulging challenges with medication adherence, oncologists who do not inquire about a patient's medication taking behaviors before making treatment changes may be making dose adjustments and other decisions based on erroneous or incomplete information. In the oncology setting where medication overuse and underuse are known to exist[18–22,34], failure to inquire about medication adherence can lead to avoidable

treatment toxicities as well as avoidable disease progression or even premature death. Standards put forth by ASCO and others[3,4], clearly advocate for the periodic assessment of not only whether or not a patient continues to take their prescribed medication, but how they are taking it. As evidenced by commonly used medication counseling strategies, such discussions should include periodic assessments of the barriers patients may face in taking prescribed medications as directed.[10]

While oncologists consistently inquired about the presence of side effects, they often do not provide patients with a self-management strategy before the patient presents with a symptom. Such an omission is increasingly costly not only to the wellbeing of patients, but also to organizations responsible for delivering their care as studies have repeatedly found side effects to be a contributing factor in costly visits to the emergency department among cancer patients being treated with chemotherapy.[35–37] In addition to adhering to national quality standards, oncology practices may implement specific protocols for building knowledge in the patients' ability to not only take their prescribed chemotherapy properly, but also identifying and managing its associated side effects before they progress in severity. This presents an opportunity to utilize other members of the healthcare team, such as pharmacists, in the patient's oncologic care. Some pharmacist-led interventions have previously shown success in the early detection of side effects and subsequently lower hospitalizations.[38–41]

To our knowledge, our study is the first to use office visit audio-recordings to evaluate patient-oncologist medication counseling discussions within oncology care. Despite the advantages of such observational data from an existing database of national scope, its use introduces a number of limitations. First, although visits were drawn from a national sample, office visits represent a convenience sample of oncology visits and observed discussions may not

representative of oncologist medication counseling more broadly. Compounding this is our inability to describe either the patient or oncologist sample in more detail. As such, we are not able to provide additional contextual information regarding either patients' clinical (e.g., where within a treatment course patients were or their prescribed dosing) or social (e.g., educational attainment or health literacy) characteristics. In addition, because oncology care usually is provided by clinical teams that include advanced practitioners and pharmacists, by focusing solely on patient-oncologist discussions we may miss important medication counseling delivered by others. As such, we cannot draw conclusions regarding all medication counseling received by oncology patients, but only that provided by an oncologist during office visits. Nonetheless, the counseling received during such visits seems particularly relevant both because of the importance patients place on this as an information source[23], and because of the need for physicians to understand patient medication adherence before altering therapy. Future longitudinal studies focusing on medication counseling delivered by other members of the oncology care team are needed to provide further insight into these issues. Of note, however, is the fact that no patient-oncologist discussion mentioned a medication support program or other clinician available to assist the patient with their medications. In addition, although the importance of patient-physician office visit communication to patient outcomes in other clinical contexts has been shown[24,25], a limitation of the current study is the inability to link identified communication behaviors with patient adherence and other outcomes.

Using audio-recordings from a national sample of patient-oncologist office visits, we identified a number of potentially important opportunities to enhance oncologists' medication counseling. Among these is the opportunity for oncologists to assess how patients are taking prescribed therapy and to offer side effect symptom management strategies to patients before

they present with symptom burden. As reliance on oral cancer treatment expands, it is increasingly important to understand how patient-oncologist office visit discussions can best support patients' adherence to oral chemotherapy treatment.

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Table 1. Patient Sample Characteristics (N=24)

Age	
19-34	1 (4%)
35-54	7 (29%)
55-74	10 (42%)
75+	6 (25%)
Sex	
Male	9 (38%)
Female	15 (62%)
Race	
White	19 (79%)
Other	5 (21%)
Treatment Status	
Pre-treatment Initiation	5 (21%)
Mid-treatment	18 (75%)
Unknown	1 (4%)
Concomitant Infusions	
Bevacizumab	2 (8%)
Fluorouracil	1 (4%)
Irinotecan	1 (4%)
Oxaliplatin	10 (42%)
None	11 (46%)
Caregiver	
Present	12 (50%)